State of Georgia
Department of Natural Resources
Environmental Protection Division
Air Protection Branch

AIR QUALITY PERMIT

Permit No.
3841-217-0021-S-03-0

Effective Date
APR 0 8 2010

In accordance with the provisions of the Georgia Air Quality Act, O.C.G.A. Section 12-9-1, et seq and the Rules, Chapter 391-3-1, adopted pursuant to and in effect under that Act,

Facility Name: **Bard Medical Division, Covington**

Mailing Address: 8195 Industrial Blvd.
Covington, GA 30014

is issued a Permit for the following:

Operation of an ethylene oxide sterilization facility. Construction and operation of a new sterilization line to include one new sterilization vessel and two new aeration cells. This Permit is issued for the purpose of establishing practically enforceable emission limitations such that the facility will not be considered a major source with respect to Title V of the Clean Air Act Amendments of 1990.

Facility Location: 8195 Industrial Blvd.
Covington, GA 30014 (Newton County)

This Permit is conditioned upon compliance with all provisions of The Georgia Air Quality Act, O.C.G.A. Section 12-9-1, et seq, the Rules, Chapter 391-3-1, adopted and in effect under that Act, or any other condition of this Permit.

This Permit may be subject to revocation, suspension, modification or amendment by the Director for cause including evidence of noncompliance with any of the above; or for any misrepresentation made in Application No. 18737 dated January 20, 2009 and Application 19408 dated December 30, 2009; any other applications upon which this Permit is based; supporting data entered therein or attached thereto; or any subsequent submittals or supporting data; or for any alterations affecting the emissions from this source.

This Permit is further subject to and conditioned upon the terms, conditions, limitations, standards, or schedules contained in or specified on the attached **8** pages.

J. Allen Barnes
Director
Environmental Protection Division

1. General Requirements

1.1 At all times, including periods of startup, shutdown, and malfunction, the Permittee shall maintain and operate this source, including associated air pollution control equipment, in a manner consistent with good air pollution control practice for minimizing emissions. Determination of whether acceptable operating and maintenance procedures are being used will be based on information available to the Division which may include, but is not limited to, monitoring results, opacity observations, review of operating and maintenance procedures, and inspection or surveillance of the source.

1.2 The Permittee shall not build, erect, install or use any article, machine, equipment or process the use of which conceals an emission which would otherwise constitute a violation of an applicable emission standard. Such concealment includes, but is not limited to, the use of gaseous diluents to achieve compliance with an opacity standard or with a standard that is based on the concentration of a pollutant in the gases discharged into the atmosphere.

1.3 The Permittee shall submit a Georgia Air Quality Permit application to the Division prior to the commencement of any modification, as defined in 391-3-1-.01(pp), which may result in air pollution and which is not exempt under 391-3-1-.03(6). Such application shall be submitted sufficiently in advance of any critical date involved to allow adequate time for review, discussion, or revision of plans, if necessary. The application shall include, but not be limited to, information describing the precise nature of the change, modifications to any emission control system, production capacity and pollutant emission rates of the plant before and after the change, and the anticipated completion date of the change.

1.4 Unless otherwise specified, all records required to be maintained by this Permit shall be recorded in a permanent form suitable for inspection and submission to the Division and shall be retained for at least five (5) years following the date of entry.

1.5 In cases where conditions of this Permit conflict with each other for any particular source or operation, the most stringent condition shall prevail.

2. Allowable Emissions

2.1 The Permittee shall comply with all applicable provisions of the National Emission Standard for Hazardous Air Pollutants (NESHAP) as found in 40 CFR Part 63 Subpart O, "Ethylene Oxide Emission Standards from Sterilization Facilities" for the operation of the ethylene oxide sterilization equipment.
[40 CFR 63 Subpart O; 40 CFR 63.360]

2.2 The Permittee shall comply with all applicable provisions of 40 CFR Part 63 Subpart A – "General Provisions" as specified in Table 1 of 40 CFR 63 Subpart O.
[40 CFR 63 Subpart A; 40 CFR 63.360]

2.3 The ethylene oxide emissions to the atmosphere from each sterilizer chamber vent shall be reduced by at least 99%.
[40 CFR 63 Subpart O; 40 CFR 63.362(c); 40 CFR 70 Avoidance for HAP and VOC]

2.4 The Permittee shall either reduce ethylene oxide emissions from each aeration room vent to 1 ppm by volume or less or by at least 99%.
[40 CFR 63 Subpart O; 40 CFR 63.362(d); 40 CFR 70 Avoidance for HAP and VOC]

2.5 The emission limitations of Condition Nos. 2.3. and 2.4 apply during sterilization operation. The emission limits do not apply during periods of malfunction.
[40 CFR 63 Subpart O; 40 CFR 63.362(b)]

2.6 The Permittee shall comply with the emissions limitations of 40 CFR Part 63, Subpart O as follows:

a. All sterilization chamber vents with an initial startup date after December 6, 1998 shall comply immediately upon initial startup of the source.

b. All aeration room vents with an initial startup date on or after December 6, 2000, shall comply immediately upon initial startup of the source.

[40 CFR 63 Subpart O; 40 CFR 63.360(g)]

3. Fugitive Emissions

3.1 The Permittee shall take all reasonable precautions with any operation, process, handling, transportation, or storage facilities to prevent fugitive emissions of air contaminants.

4. Process & Control Equipment

4.1 The Permittee shall operate the Regenerative Thermal Oxidizer (RTO-1) at or above 1447 degrees Fahrenheit (or a new minimum oxidation temperature approved in writing by the Division), except during periods of startup, shutdown, or malfunction. An operating parameter deviation is defined as any 24-hour average of the oxidation temperature for the Regenerative Thermal Oxidizer (RTO-1) that is below 1447 degrees Farenheit (or a new minimum oxidation temperature approved in writing by the Division) The Permittee may establish a new minimum oxidation temperature based on performance testing and that is at least equal to or higher than the recommended minimum oxidation temperature provided by the Regenerative Thermal Oxidizer (RTO-1) manufacturer.
[40 CFR 63 Subpart O; 40 CFR 63.363(b)(3), 40 CFR 63 363(f)]

4.2 Routine maintenance shall be performed on all air pollution control equipment. Maintenance records shall be recorded in a permanent form suitable and available for inspection by the Division. The records shall be retained for at least five years following the date of such maintenance.

4.3 A spare parts inventory for control equipment shall be maintained by the Permittee.

4.4 Malfunctioning components of air pollution control systems shall be repaired as expeditiously as possible.

5. Monitoring

5.1 The Permittee shall either continuously monitor and record the oxidation temperature using the temperature monitor(s) described in Condition 5.2 or measure and record the ethylene oxide concentration in accordance with §63.364(e). Monitoring is required only when the Regenerative Thermal Oxidizer (RTO-1) is operated.
[40 CFR 63 Subpart O; 40 CFR 63.364(c)]

5.2 The Permittee shall install, calibrate, maintain, and operate a system to continuously monitor and record the oxidation temperature as determined from the average reading of the three combustion chamber temperature sensors on the Regenerative Thermal Oxidizer (RTO-1). Monitoring is required only when Regenerative Thermal Oxidizer (RTO-1 is operated. The temperature monitor shall be accurate within ±5.6 degrees Celsius (± 10 degrees Fahrenheit). Where such performance specification(s) exist, each system shall meet the applicable performance specification(s) of the Division's monitoring requirements.
[40 CFR 63 Subpart O; 40 CFR 63.364(c)]

5.3 The Permittee shall verify the accuracy of the temperature monitor required by Condition No. 5.2 twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).
[40 CFR 63 Subpart O; 40 CFR 63.364(c)(4)]

5.4 Any monitoring system installed by the Permittee shall be in continuous operation except during calibration checks, zero and span adjustments or periods of repair. Maintenance or repair shall be conducted in the most expedient manner to minimize the period during which the system is out of service.

5.5 The Permittee shall provide and maintain a spare parts inventory for any monitoring system installed. A list of parts to be kept in inventory shall be kept in a form suitable for inspection by the Division for no less than five years.

6. Performance Testing

6.1 The Permittee shall cause to be conducted a performance test at any specified emission point when so directed by the Division. The following provisions shall apply with regard to such tests:

a. All tests shall be conducted and data reduced in accordance with applicable procedures and methods specified in the Division's Procedures for Testing and Monitoring Sources of Air Pollutants.

b. All test results shall be submitted to the Division within sixty (60) days of the completion of testing

c. The Permittee shall provide the Division thirty (30) days (or sixty (60) days for test required by 40 CFR Part 63) prior written notice of the date of any performance test(s) to afford the Division the opportunity to witness and/or audit the test, and shall provide with the notification a test plan in accordance with Division guidelines.

d. All monitoring systems and/or monitoring devices required by the Division shall be installed, calibrated and operational prior to conducting any performance test(s). For any performance test, the Permittee shall, using the monitoring systems and/or monitoring devices, acquire data during each performance test run. All monitoring system and/or monitoring device data acquired during the performance testing shall be submitted with the performance test results.

6.2 Within 60 days of achieving the maximum production rate for Sterilization Vessel # 5 (Source Code SV5), but not later than 180 days after startup, the Permittee shall conduct ethylene oxide performance testing to determine compliance with the emission limit in Condition 2.3 in accordance with the procedures listed in 40 CFR 63.7 according to the applicability in Table 1 of 40 CFR 63.360, the procedures listed in 40 CFR 63.363, and the test methods listed in 40 CFR 63.365.
[40 CFR 63 Subpart O; 40 CFR 63.363 and 63.365]

6.3 Within 60 days of achieving the maximum production rate for Aeration Cell 5A (Source Code A5A) and Aeration Cell 5B (Source Code A5B), but not later than 180 days after startup, the Permittee shall conduct ethylene oxide performance testing to determine compliance with the emission limit in Condition 2.4 in accordance with the procedures listed in 40 CFR 63.7 according to the applicability in Table 1 of 40 CFR 63.360, the procedures listed in 40 CFR 63.363, and the test methods listed in 40 CFR 63.365.
[40 CFR 63 Subpart O; 40 CFR 63.363 and 63.365]

6.4 In accordance with 40 CFR 63.7(b) and 63.9(e), the Permittee shall notify the Division of intent to conduct a performance test at least 60 calendar days before the performance test is scheduled to begin. If the test must be rescheduled due to unforeseeable circumstances beyond his control, the Permittee shall notify the Division within five (5) days prior to the scheduled date of the test and shall specify the date when the test is rescheduled.

6.5 In accordance with 40 CFR 63.7(c)(4), the Permittee shall analyze performance audit samples during each performance test.

6.6 The Permittee shall provide performance testing facilities as specified in 40 CFR 63.7(d). Performance tests shall be conducted under conditions based on representative performance of the source and as otherwise specified in 40 CFR 63.7(e).

6.7 In accordance with 40 CFR 63.7(c)(2), the Permittee shall submit a site-specific test plan along with the Notification of Intent to conduct a performance test.

6.8 In accordance with 40 CFR 63.7(g), 63.9(h), 63.10(d), and 63.366(a), the Permittee shall submit the results of a performance test within 60 days following completion of the test.

7. Notification, Reporting and Record Keeping Requirements

7.1 The Permittee shall maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, any malfunction of the air pollution control equipment or any periods during which a continuous monitoring system or monitoring device is inoperative. The Permittee shall retain these records for a period of at least five (5) years after the date of any such startup, shutdown, or malfunction.

7.2 In the event of any malfunction or breakdown of process or emission control equipment for a period of four hours or more which results in excessive emissions, the owner or operator shall submit a written report which describes the cause of the breakdown, the corrective actions taken, and the plans to prevent future occurrences. This report must be submitted by means that would ensure the Division's receipt of the report by no later than seven days after the occurrence. The information submitted shall be adequate to allow the Division to determine if the excessive emissions were due to a sudden and unavoidable breakdown. Such a report shall in no way serve to excuse, otherwise justify or in any manner affect any potential liability or enforcement action.

7.3 The Permittee shall maintain a file of all measurements, including continuous monitoring system, monitoring device, and performance testing measurements; all continuous monitoring system performance evaluations; all continuous monitoring system or monitoring device calibration checks; adjustments and maintenance performed on these systems or devices; and all other information required by this Permit. The information shall be recorded in a permanent form suitable and available for inspection and shall be retained for at least five (5) years following the date of such measurements maintenance, reports, and records

7.4 The data acquisition system for the temperature monitors required by Condition 5.2 shall compute and record a daily average oxidation temperature from the 15-minute or shorter period temperature values. Strip chart data shall be converted to record a daily average oxidation temperature for each day any instantaneous temperature recording falls below the minimum temperature.
[40 CFR 63 Subpart O; 40 CFR 63.364(c)]

7.5 The Permittee shall maintain files of all information required by this permit or by 40 CFR 63 in a form suitable and available for expeditious inspection and review for at least five years following date of entry in accordance with 40 CFR 63.10(b)(1).

7.6 The Permittee shall maintain General records and CMS records as specified by 40 CFR 63.10(b)(2) and (c), respectively, and Table 1 of 40 CFR 63 Subpart O

7.7 In accordance with 40 CFR 63.10, 63.366(a), and Table 1 of 40 CFR 63 Subpart O, the Permittee shall submit the following reports:

a. Deviation reports; and

b. Continuous Monitoring System performance and summary reports

Contents and submittal dates for Deviation and Continuous Monitoring System Performance Reports shall be as specified in 40 CFR 63.366(a)(3).

7.8 The Permittee shall submit a written report containing any excess emissions, exceedances, and/or excursions as described in this permit and any monitor malfunctions for each semiannual period ending June 30th and December 31st of each year. All reports shall be postmarked by the 30th day following the end of each reporting period, July 30th and January 30th. In the event that there have not been any excess emissions, exceedances, excursions, or malfunctions during a reporting period, the report should so state. Otherwise, the contents of each report shall be as specified by the Division's Procedures for Testing and Monitoring Sources of Air Pollutants and shall contain the following:
[391-3-1-.02(6)(b)1, 40 CFR 63.10(e)]

a. A summary report of excess emissions, exceedances and excursions, and monitor downtime, in accordance with Section 1.5(c) and (d) of the above referenced document, including any failure to follow required work practice procedures.

b. Total process operating time during each reporting period.

c. The magnitude of all excess emissions, exceedances and excursions computed in accordance with the applicable definitions as determined by the Director, and any conversion factors used, and the date and time of the commencement and completion of each time period of occurrence.

d Specific identification of each period of such excess emissions, exceedances, and excursions that occur during startups, shutdowns, or malfunctions of the affected facility. Include the nature and cause of any malfunction (if known), the corrective action taken or preventive measures adopted.

e. The date and time identifying each period during which any required monitoring system or device was inoperative (including periods of malfunction) except for zero and span checks, and the nature of the repairs, adjustments, or replacement. When the monitoring system or device has not been inoperative, repaired, or adjusted, such information shall be stated in the report.

f. Certification by a Responsible Official that, based on information and belief formed after reasonable inquiry, the statements and information in the report are true, accurate, and complete.

7.9 The Permittee shall furnish the Division written notification as follows:

a. The date of construction of Sterilization Vessel # 5 (Source Code: SV5), Aeration Cell 5A (Source Code: A5A), and Aeration Cell 5B (Source Code: A5B) no later than 30 days after such date.

b. The anticipated date of initial startup of Sterilization Vessel # 5 (Source Code: SV5), Aeration Cell 5A (Source Code: A5A), and Aeration Cell 5B (Source Code: A5B), not more than 60 nor less than 30 days prior to such date.

c. The actual date of initial startup of Sterilization Vessel # 5 (Source Code: SV5), Aeration Cell 5A (Source Code: A5A), and Aeration Cell 5B (Source Code: A5B) within 15 days after such date.

d Certification that a final inspection has shown that construction has been completed in accordance with the application, plans, specifications, and supporting documents submitted in support of this Permit.

For the purposes of this Permit, "startup" shall mean the setting in operation of a source for its intended purpose.
[40 CFR 63 Subpart O; 40 CFR 63.366(c)(1)(ii)]

8. Special Conditions

8.1 At any time that the Division determines that additional control of emissions from the facility may reasonably be needed to provide for the continued protection of public health, safety and welfare, the Division reserves the right to amend the provisions of this Permit pursuant to the Division's authority as established in the Georgia Air Quality Act and the rules adopted pursuant to that Act.

8.2 The Permittee shall calculate and pay an annual Permit fee to the Division. The amount of the fee shall be determined each year in accordance with the "Procedures for Calculating Air Permit Fees."

8.3 Georgia Air Quality Permit No. 3841-217-0021-V-02-0, is hereby revoked in its entirety

Georgia Department of Natural Resources
Environmental Protection Division • Air Protection Branch
4244 International Parkway • Suite 120 • Atlanta • Georgia 30354
404/363-7000 • Fax: 404/363-7100
Chris Clark, Commissioner
F. Allen Barnes, Director

APR 0 8 2010

John LaMontagne
Manager, Facility Engineering
C.R. Bard, Incorporated
8195 Industrial Blvd.
Covington, GA 30014

Re: Synthetic Minor Applications No. 18737, Dated January 20, 2009 and No. 19408 Dated December 30, 2009
Facility AIRS No. : 21700021

Dear Mr. LaMontagne:

Enclosed please find Air Quality Permit No. 3841-217-0021-S-03-0 for the construction and operation of one new Sterilization Vessel and two new Aeration Cells at Bard Medical Division, Covington in Covington, Georgia. The permit also reclassifies the site as a synthetic minor source and allows the operation of existing equipment. Please be aware that a Title V Annual Compliance Certification and a semiannual report is due for the period of time that the Title V permit was active. Please contact your compliance engineer if you have any questions regarding the submittal of these reports.

Note that any future modifications that might affect potential emissions from your facility will require review and possible permitting through this office.

The following types of correspondence should be sent to the Division personnel indicated:

- Testing: Ross Winne – Program Manager, Industrial Source Monitoring Program
- Monitoring and Compliance (reports): Karen Hays - Unit Manager, Stationary Source Compliance Program.

Thank you for your cooperation. If you have any questions or need more information, please contact me at (404) 362-4844 or via email at amy.young@*dnr.state.ga.us*.

Sincerely,

Amy Young

Amy Young
Environmental Engineer
Stationary Source Permitting Program

Enclosure

c: SSCP, Lynn Rhodes